

IFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

International application of :  
Shigeru CHIKASE et al. : **Mail Stop: PCT**  
Serial No. 10/574,979 : Attorney Docket No. 2006\_0391A  
Filed April 7, 2006 :

AMORPHOUS ANTIBIOTIC COMPOSITION  
COMPRISING CEFDITOREN PIVOXIL

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEE FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975.

**SUBMISSION OF ENGLISH TRANSLATION OF  
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

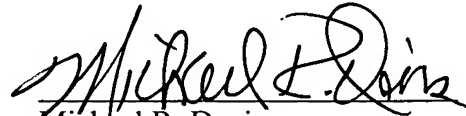
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants are submitting herewith a copy of Form PCT/IB/338 together with a copy of the International Preliminary Report on Patentability including the Written Opinion.

Respectfully submitted,

Shigeru CHIKASE et al.

By:   
Michael R. Davis  
Registration No. 25,134  
Attorney for Applicants

MRD/pth  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
January 26, 2007

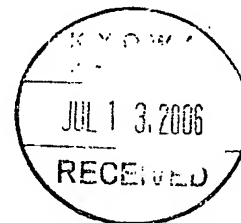
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

YOSHITAKE, Kenji  
Kyowa Patent & Law Office  
Room 323, Fuji Bldg.  
2-3, Marunouchi 3-chome  
Chiyoda-ku Tokyo 1000005  
JAPON



Date of mailing (day/month/year) 06 July 2006 (06.07.2006)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference 149111-193	
International application No. PCT/JP2004/014840	International filing date (day/month/year) 07 October 2004 (07.10.2004)
Applicant MEIJI SEIKA KAISHA, LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Yoshiko Kuwahara
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 149111-193	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2004/014840	International filing date ( <i>day/month/year</i> ) 07 October 2004 (07.10.2004)	Priority date ( <i>day/month/year</i> ) 08 October 2003 (08.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant MEIJI SEIKA KAISHA, LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 26 June 2006 (26.06.2006)  Authorized officer  <p style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</p> e-mail: pt07@wipo.int
---	--

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

**TRANSLATION**  
**PCT**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**149111-193**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/014840**

International filing date (day/month/year)

**07.10.2004**

Priority date (day/month/year)

**08.10.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**MEIJI SEIKA KAISHA, LTD.**

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/IP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/014840

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/014840

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP, 2001-131071, A (Meiji Seika Kabushiki Kaisha), 15 May, 2001 (15.05.01)  
Document 2: JP, 7-17866, A (Meiji Seika K.K.), 20 January, 1995 (20.01.95)  
Document 3: WO, 02-87588, A1 (Meiji Seika K.K.), 07 November, 2002 (07.11.02)  
Document 4: WO, 96-19239, A1 (Yamanouchi Pharmaceutical Co., Ltd.), 27 June, 1996 (27.06.96)  
Document 5: JP, 2003-26676, A (Takeda Chemical Industries, Ltd.), 29 January, 2003 (29.01.03)  
Document 6: WO, 00-04896, A1 (Yamanouchi Pharmaceutical Co., Ltd.), 03 February, 2000 (03.02.00)

The subject matters of claims 1-10 do not appear to involve an inventive step according to documents 1-6 cited in the ISR.

In documents 1-3, non-crystalline cefditoren pivoxil and a preparation that contains it is described, as well as the said preparation obtained for oral administration (document 1, claims 1-10; document 2, claims 1-2 and paragraph [0001]; document 3 claims 1-11). Also, in documents 2 and 3, the combining of a water-soluble polymer is described (document 2, claims 1-2; document 3, claim 2).

In document 4-6, the improvement of absorption of an insoluble drug from the gastrointestinal tract based on combining a polymer base and a sucrose/fatty acid ester non-ionic surfactant is described (document 4, claims 1-12; document 5, claims 1-17 and paragraph [0001]; document 6, claims 1-8). Moreover, in document 4, non-crystallization of an insoluble drug and, when a solid composition having a polymer base and a non-ionic surfactant is dispersed in a liquid, the non-crystalloid being preserved over a long period of time is described (document 4, page 2, lines 19-24).

Accordingly, in the subject matters described in claims 1-3, combining a polymer base described in documents 4-6 and a non-ionic surfactant for improving the absorption of an effective component is easily conceivable for a person skilled in the art and is not recognized as being an exceptional effect.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/014840

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
JP 2004-175779 A [E, X]	24.06.2004	03.03.2003	02.10.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
---------------------------------------	--	--

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/014840

Box No. VIII      Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The subject matters of claims 1, 2, 4, are unclear due to the description of "favorable" and "more favorable".